TRUMP ADMINISTRATION DRUG PRICING PLAN WOULD TIE MEDICARE PART B REIMBURSEMENT TO INTERNATIONAL PRICES

Date: 2 November 2018

Health Care Alert

By: Zachary W. Ernst, Richard P. Church

On October 25, the Centers for Medicare and Medicaid Services ("CMS") issued an Advance Notice of Proposed Rulemaking ("ANPRM") seeking input on the development of a new drug pricing model under Medicare Part B to index reimbursement for drugs to drug costs in "economically-similar countries," titled the International Pricing Index ("IPI Model"). The ANPRM was published in the Federal Register on October 30 [1] and follows up on other recent drug pricing proposals from the Trump administration, including the administration's drug pricing blueprint released on May 11, 2018 (see here for our prior analysis).

In summary, the IPI Model would:

> • Pay a new IPI Model vendor directly for Part B drugs at a benchmarked international price.
>
> • Pay physicians and hospitals a per-month or per-dispense administration fee, which would solely compensate them for the cost of administration and would not be tied in any direct manner to the cost of the drug administered.

Accordingly, one of the primary effects of the IPI Model would be to remove health systems and hospitals from billing for certain Part B drugs altogether.

CMS is requesting public feedback on how to develop the model, which is discussed in detail below, by Monday, December 31, 2018.

A full summary of the ANPRM is set forth below.

MEDICARE PAYMENTS UNDER THE IPI MODEL

The IPI Model would align Medicare payments for Part B drugs with international prices. [2] In this regard, CMS notes that based on one analysis of drug acquisition costs, "acquisition costs in the U.S. were 1.8 times higher" for 27 Medicare Part B physician-administered drugs than in comparable countries, including Canada, Japan, and in Europe. Accordingly, Medicare would pay IPI Model vendors based on pricing data from Austria, Belgium, Canada, the Czech Republic, Denmark, Finland, France, Germany, Greece, Ireland, Italy, Japan, the Netherlands, and the United Kingdom. [3] Medicare would then pay new private sector vendors in selected

geographic areas to supply physicians, hospital outpatient departments, and other providers and suppliers with drugs subject to the IPI Model. [4]

Under the IPI Model, physicians and hospitals would only be paid an alternative drug add-on payment for dispensing that is based on a set payment amount per encounter or per month — rather than the current 6% add-on that reflects a percentage of the drug's average sales price (ASP) — in order to eliminate incentives to prescribe higher-cost drugs. [5] CMS would calculate what would have been paid before sequestration in the absence of the model for administration of the drug — i.e., the current 6% add-on for all drugs in the aggregate — and then redistribute this amount to model participants based on a set payment amount per dispense or per month that would not be tied directly to the drugs costs. [6]

CMS contemplates that the add-on payment would be based on the class of drug, the physician's specialty, or the physician's practice. [7] CMS is also considering a bonus pool where participants would achieve bonus payments for prescribing lower-cost drugs or practicing evidence-based utilization. [8]

TIMING AND SCOPE OF THE IPI MODEL

In the ANPRM, CMS indicates that it is considering issuing a proposed rule on the IPI Model in spring 2019, with a start date in spring 2020 and five-year operating timeline. [9]

The IPI Model would focus on "selected separately payable Part B drugs and biologicals" ("IPI Drugs") and include physicians, hospitals, and potentially other providers and suppliers in selected geographic areas, which CMS anticipates would cover 50% of Medicare Part B spending on separately payable drugs. [10] As proposed, CMS would first include single source drugs and biologicals, including (i) cancer drugs and adjunct therapy for cancer and related conditions; (ii) biologicals used for the treatment of rheumatoid arthritis and other immune-mediated conditions; and (iii) drugs used to treat macular degeneration. [11] In particular, in Years 1–2, CMS would include "single source drugs, biologicals, biosimilars, and multiple source drugs with a single manufacturer" as IPI Drugs. [12] In Years 3-5, CMS would broaden the scope to include more single-source drugs and biologicals, as more sources of international pricing data became available. [13] Payments for such drugs over the five-year period would be designed to phase in to meet a specified target price that would be based, in part, on international pricing. [14] However, CMS may exclude: (i) drugs that are identified by the FDA to be in short supply; (ii) drugs paid under miscellaneous or "not otherwise classified" codes; (iii) radiopharmaceuticals and ESRD drugs; and (iv) drugs that are packaged under the Outpatient Prospective Payment System ("OPPS") when they are furnished by a hospital outpatient department. [15]

Participation would be mandatory for the physician practices, hospital outpatient departments, and other potential providers and suppliers that would furnish IPI Drugs in the selected geographic regions. [16] IPI Model vendors, rather than health care providers, would take on the financial risk of acquiring the drugs and billing Medicare. [17]

Outside of the designated geographic regions and for non-IPI Drugs, physicians and hospitals would continue to purchase and bill under current Medicare Fee-For-Service payment policies. [18]

IPI MODEL VENDORS

Entities such as GPOs, wholesalers, distributors, specialty pharmacies, individual or groups of physicians and hospitals, manufacturers, Part D sponsors, and/or other entities could operate as IPI Model vendors as long as they could satisfy the vendor qualification requirements. Vendor responsibilities would be specified in a model vendor agreement. [19]

CMS notes that IPI Model vendors would have flexibility to offer delivery mechanisms such as electronic ordering, frequent delivery, and onsite stock replacement programs, to encourage physicians and hospitals to obtain drugs through the vendor. [20] Vendors and providers would negotiate the terms of the arrangement with appropriate guardrails to protect beneficiaries and the Medicare program — in this regard, CMS requests comments on whether CMS should be a party to and/or regulate these agreements, including whether the agreements should specify obligations to ensure the safety and integrity of the drugs, how drug disposition would be handled, data sharing methods, confidentiality, and potentially other requirements. [21]

Physicians and hospitals in the IPI Model would be able to select their preferred vendors, engage with multiple vendors for different drugs, and change vendors. [22] In addition, as noted above, the IPI Model would pay physicians and hospitals a "drug add-on amount" that would be structured differently from the current drug add-on amount paid by Medicare for drug administration. [23]

IMPACT ON THE 340B PROGRAM

For covered entities under the 340B Program in the selected geographic areas, the IPI Model could have a significant detrimental effect on the 340B revenue opportunity providers are able to realize as it relates to the margin on Part B drugs, due to the fact that IPI Model vendors would purchase the drugs and receive payment for the drugs from Medicare. It is also worth noting that Medicare has already reduced the potential 340B margin on such drugs through the CY 2018 OPPS Final Rule (which generally cut 340B drug reimbursement to ASP-22.5%) and the CY 2019 OPPS Proposed Rule (which would apply the same cut to nonexcepted, off-campus provider based departments under the Medicare site-neutral rule). See here for prior analysis of the CY 2019 Proposed Rule. [24]

In addition, the 340B ceiling price is calculated based on a drug's Average Manufacturer Price ("AMP") net the Medicaid unit rebate amount. Since the Medicaid unit rebate amount is based partly on AMP minus best price, to the extent the IPI Model affects a drug's AMP and best price, 340B prices from manufacturers could be affected. [25]

PUBLIC COMMENT OPPORTUNITY

CMS is requesting public feedback on how to develop the model. As an overview of the topics for public comment that require feedback, CMS provides the following list of overarching questions:

- What limitations would be in place on the entities that could participate as vendors (e.g., pharmacies, manufacturers, providers themselves)?

- Which countries should be included in calculating an international pricing index? How frequently should international data be updated?
- What should be the schedule for phasing in the spending target?
- Should we introduce health care provider bonuses to incentivize reductions in cost or utilization relative to a benchmark? [26]

In issuing the ANPRM, CMS cites its authority under Section 1115A of the Social Security Act to test models that are "expected to reduce program expenditures, while preserving or enhancing the quality of care furnished to beneficiaries." [27] As with other recent Medicare drug pricing changes, CMS's authority to implement the IPI Model will likely also be a subject of comment and potential legal challenge.

INDUSTRY REACTION

In response to the proposal, the Pharmaceutical Research and Manufacturers of America ("PhRMA") responded immediately, pushing back against the administration for attempting to impose "foreign price controls from countries with socialized health care systems that deny their citizens access and discourage innovation." [28] Trade organizations representing providers were more muted in their remarks, particularly given the lack of specificity in the ANPRM — for example, American Hospital Association (AHA) President and CEO Rick Pollack said, "America's hospitals and health systems are pleased that President Trump and his administration are focused on reining in out-of-control drug prices . . . We look forward to reviewing the details of the model closely, including its impact on 340B hospitals and the patients they serve." [29]

NEXT STEPS

Given that the potential IPI Model would represent a major shift in Medicare Part B drug reimbursement policy, health systems, hospitals, and other providers and suppliers who anticipate being impacted by the potential IPI Model may want to submit comments to CMS regarding the ANPRM. In this regard, it is likely the IPI Model will be the subject of intense lobbying efforts from all stakeholders in the pharmaceutical manufacturing and distribution chain. In addition to the merits of the IPI Model, there will likely also be intense focus on the exact scope and structure of the IPI Model, particularly key issues such as geographies and drugs included and the criteria for enrolling as a drug vendor to physicians and hospitals in the IPI Model.

K&L Gates' health care practice can assist health systems and hospitals, and other providers and suppliers in responding to the ANPRM and assessing how the potential IPI Model would impact them. We regularly advise clients on 340B Program implementation and compliance matters and facilitate stakeholder engagement with Congress, the Trump administration, and CMS through our public policy and law practice. We will continue to closely monitor developments related to this ANPRM, Medicare Part B drug reimbursement, and 340B Program changes.

NOTES:

[1] Medicare Program; International Pricing Index Model for Medicare Part B Drugs, 83 Fed. Reg. 54546 (Oct. 30, 2018), https://www.gpo.gov/fdsys/pkg/FR-2018-10-30/pdf/2018-23688.pdf.
[2] Id.
[3] Id. at 54550.
[4] Id.
[5] Id. at 54547
[6] Id.
[7] Id. at 54553
[8] Id.
[9] Id.
[10] Id.
[11] Id. at 54554
[12] Id.
[13] Id.
[14] Id. at 54556
[15] Id. at 54555
[16] Id. at 54552
[17] Id. at 54550
[18] Id.
[19] Id.
[20] Id.
[21] Id.
[22] Id.
[23] Id. at 54553
[24] There is also risk that the IPI Model will have unintended consequences impacting the 340B Program. For instance, due to the fact that IPI Model vendors would negotiate with manufacturers on behalf of all entities contracted with that vendor, there is risk that obtaining drugs in this manner would violate the 340B Program's GPO Prohibition, which prohibits covered entities broadly from obtaining drugs through any group purchasing arrangement. However, it is notable that the ANPRM does not specifically address the 340B Program other than to note that 340B covered entities would participate, and given the preliminary stage of the rulemaking process and lack of specifics, the risk appears to be quite low and simply an unintended theoretical consequence of the ANPRM.
[25] Id. at 54559
[26] Id. at 54550
[27] Id. at 54559
[28] Press Release, PhRMA, PhRMA Statement on HHS Speech and Part B Proposal, Oct. 25, 2018, https://www.phrma.org/press-release/phrma-statement-on-hhs-speech-and-part-b-proposal.
[29] Press Release, AHA, CMS Seeks Comments on Potential New Payment Model for Part B Drugs, Oct. 25, 2018, https://www.aha.org/news/headline/2018-10-25-cms-seeks-comments-potential-new-payment-model-part-b-drugs.

